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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,164	08/30/2006	Naoki Nagahara	2006_1328A	6045
513 7590 03/03/2011 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
DICKINSON, PAUL W				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
03/03/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
coa@wenderoth.com

Advisory Action
Before the Filing of an Appeal Brief

Application No.

10/591,164

Applicant(s)

NAGAHARA ET AL.

Examiner

PAUL DICKINSON

Art Unit

1618

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 February 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 2, 4, 5, 12 and 14-24.
Claim(s) withdrawn from consideration: 3, 6 and 13.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/PAUL DICKINSON/
Examiner, Art Unit 1618

Continuation of 11, does NOT place the application in condition for allowance because: The rejection of claims 1-2, 4-5, 12, and 14-24 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) in view of US 6887307 ('307) is maintained for the reasons of record.

Applicant argues that there is no motivation to combine '052 and '307, as '052 relates to a composition comprising lansoprazole (which is unstable to acids) while '307 is to a capsule comprising acidic substances. Exposure of lansoprazole to acidic substances within a capsule (as indicated by '307) would radically change the principle of operation of '052 as lansoprazole is unstable to acids.

Applicant's arguments have been fully considered but are not found persuasive. The underlying assumption of applicant's argument is that combination of '052 and '307 requires incorporation of an acid in the pullulan capsule. In other words, combination of '052 and '307 requires addition of an acid to lansoprazole. The examiner agrees with applicant that adding an acid to lansoprazole would radically change the principle operation of lansoprazole, as lansoprazole is unstable to acids. However, adding an acid to lansoprazole is not part of the rejection, nor is it a requisite of combining '052 and '307. The basis of the rejection is set forth in the office action mailed 12/9/2009. The basis of the rejection is to use the pullulan capsules of '307 as the capsule shell of '052. The rationale for using the pullulan capsules of '307 is that they exhibit low oxygen permeability, lower water content, and high stability. Such a capsule preparation would comprise a capsule shell made of pullulan and contained inside lansoprazole. There would be no acids present in the capsule preparation. The only mention of acids in '307 are optional acidic sequestering agents (col 5, lines 5-12). These are optional components and the ordinary artisan would understand that acidic sequestering agents should not be combined with acid sensitive lansoprazole. The examiner maintains that it would have been obvious to use the pullulan capsules of '307 as the capsule shell of '052.